Idaho Immunization Program

450 W State Street 4th FL
Boise, Idaho 83702
(208) 334-5931

2015 PROVIDER POLICIES AND GUIDELINES

PROGRAM OVERVIEW

Idaho Immunization Program

The Idaho Immunization Program (IIP) administers the federal Vaccines for Children (VFC) program in Idaho. All vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) are supplied at no cost, through a combination of federal and state dollars, for Idaho children 0 through 18 years of age. Providers must be enrolled with the IIP to receive the vaccine.

The federal dollars, provided through the Centers for Disease Control and Prevention (CDC), fund vaccines for children eligible for the VFC program. The State dollars, provided by the Idaho Immunization Assessment Board and the Idaho Department of Health and Welfare, fund vaccines for Idaho children who are not eligible for the VFC program.

Vaccines for Children Program

The federal VFC program provides vaccines at no cost to children who might not be vaccinated because of an inability to pay. The program is administered by the CDC and was created by the Omnibus Budget Reconciliation Act of 1993 as a new entitlement program to be a required part of each state's Medicaid plan.

Idaho Immunization Assessment Board

The Idaho Immunization Assessment Board was created in March 2010 after the signing of HB432. The purpose of the Board is to assess fees from health insurance carriers to fund a dedicated vaccine program which provides free vaccine for insured children (see Patient Eligibility section below).

Immunization Reminder Information System (IRIS)

IRIS is a secure, statewide immunization registry which can track, forecast, and help enrolled providers remind patients when immunizations are needed. IRIS also provides your patients with a permanent immunization record to help reduce unnecessary immunizations and save providers time when requesting patient records. IRIS is a voluntary immunization registry for people of all ages. All children born in Idaho are entered into IRIS at birth; however, anyone can notify the IIP to have some or all of his or her child's information removed from the registry.

Prior to immunization, providers must notify patients, as outlined within Title 39 Chapter 39 Section 04 of Idaho Code (http://legislature.idaho.gov/idstat/Title39/T39CH48SECT39-4804.htm) that IRIS is voluntary.

Providers must ensure that computers used by their staff to access IRIS are fully compliant with HIPAA requirements, and that their office staff who have access to IRIS are trained in the application of HIPAA to online data systems containing Personal Health Information.

In addition to any internal remediation measures taken in the event of inappropriate access to or use of IRIS within the provider's practice, the provider must also notify the IIP of the inappropriate use. Acceptable uses of IRIS are outlined within Title 39 Chapter 48 Section 03 of Idaho Code (http://legislature.idaho.gov/idstat/Title39/T39CH48SECT39-4803.htm).

Advisory Committee on Immunization Practices

The ACIP is a federal advisory panel that provides advice and guidance on the most effective means to prevent vaccine-preventable disease. Congress gave ACIP unique legal authority to determine recommendations for the routine administration of vaccine to children and practices for children and adults in the United States. The major functions of the ACIP are to:

- Develop technical recommendations on vaccine use and immunization practices;
- Harmonize immunization schedules with those of other advisory groups such as the American Academy of Pediatrics and the American Academy of Family Physicians; and
- Approve vaccines for use in the VFC Program.

After approval, ACIP recommendations are published in *Morbidity and Mortality Weekly Report* (MMWR), a scientific periodical prepared by the CDC (http://www.cdc.gov/mmwr/), and become the standard of practice for administering the applicable vaccines.

Once a new or amended recommendation is published, the ACIP approves it for inclusion in the VFC Program by passing a VFC resolution. VFC resolutions determine what vaccines are available through the VFC Program, including dosage, schedule, and contraindications. VFC resolutions are the rules that providers must follow when administering vaccines under the VFC Program.

The CDC publishes current VFC resolutions on their website at http://www.cdc.gov/vaccines/programs/vfc/acip-vfc-resolutions.htm.
Please note the following information about VFC resolutions:

- An ACIP recommendation does not apply to the VFC Program until the VFC resolution is approved.
- For newly recommended vaccines, a VFC resolution must be approved before the CDC can negotiate a purchase contract with the manufacturer. Therefore, there may be a delay between when the resolution is approved and when the vaccine is available.

All providers agree to comply with immunization schedules, dosages, and contraindications established by the ACIP and included in the VFC program unless:

- In the provider's medical judgment, and in accordance with accepted medical practice, the provider deems such compliance to be medically inappropriate; or
- The requirement(s) contradicts a parent or guardian's religious or personal beliefs.

PROVIDER ENROLLMENT

Any health care provider who serves children 0 through 18 years of age, who wants to provide childhood vaccines through the federal VFC program, who has a current license in good standing, and who has independent prescription writing authority for vaccines, may enroll with the IIP.

New Providers

Healthcare providers wishing to enroll can begin by contacting the IIP by phone (208-334-5931) or email (IIP@dhw.idaho.gov). New provider enrollment involves the following steps:

- ☐ Signing the Provider Agreement to follow the current Provider Policies and Guidelines;
- ☐ Enrolling in Idaho's Immunization Reminder Information System (IRIS);
- ☐ Supplying the required vaccine storage and handling equipment;
- ☐ Assigning staff members (primary and back-up) to be responsible for vaccine management and training; and
- ☐ Completing an enrollment site visit with IIP staff.

Once the completed paperwork has been received and processed by the IIP, a VFC pin number will be assigned. Please note that the sequence and timing of new provider enrollment activities may vary depending on your location and the availability of IIP staff. Prior to the enrollment visit, providers must have appropriate vaccine storage equipment (appropriate equipment is determined by submitting make and model information to the IIP) in place. Vaccine orders can be processed after the training has been completed and five days of current, stable, in-range temperatures (download of continuous recording device) for all vaccine storage units have been submitted to the IIP.

Re-Enrollment

Each year all vaccine providers must re-enroll with the IIP by:

- ☐ Signing the Provider Agreement to follow the current Provider Policies and Guidelines,
- ☐ Completing the Provider Profile, and
- ☐ Verifying the primary and back-up vaccine coordinators have completed the required annual education (see Required Provider Education section below).

Providers must complete an updated VFC Provider Profile any time during the year if:

- ☐ The clinic contact information changes (i.e. address, email, phone number);
- ☐ The vaccine shipping hours or instructions change (this information may be updated in IRIS by the primary and back-up vaccine management personnel at any time); or
- ☐ The facility type changes.

Providers must complete an updated Provider Agreement any time during the year if:

- ☐ The medical director (or equivalent) changes (this is the person who signed/signs the Provider Agreement); or
- ☐ The clinic ownership changes.

Providers must notify the IIP when:

- ☐ The primary or back-up vaccine coordinator changes (an email must be sent to IIP@dhw.idaho.gov);
- ☐ A staff member needs to be added, changed, or deleted from IRIS; or
- ☐ The facility adds or removes a vaccine storage unit (five days of stable temperatures must be documented before vaccine may be stored in new equipment or equipment that has been moved).

Termination

At any time, a provider may choose to terminate enrollment with the IIP. If a provider chooses to leave the program and no longer receive vaccine, then the IIP must be notified as soon as possible. In addition, the IIP may choose to terminate a provider from the program due to repeat non-compliance issues that have not been appropriately addressed or a permanent condition such as being listed on the Office of Inspector General List of Excluded Providers or the Idaho Medicaid Provider Exclusion List.

Terminated providers are required to account for all vaccine supplied by the IIP. All vaccine supplied by the IIP that is in the provider's office must be stored appropriately until arrangements can be made to have the vaccine transferred to another location, if needed. In addition, all equipment and materials supplied by the IIP must be returned. Failure to return viable vaccine and equipment to the IIP may result in reimbursement costs to the provider office. Once all vaccine and equipment have been accounted for, the IIP will issue a letter to the provider finalizing the termination.

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SPECIALTY PROVIDERS

Specialty providers are providers who offer limited care in a specialized environment or provide health care in a focused specialty area. A "specialty provider" is defined as a provider that only serves:

- A population defined by the practice specialty (e.g. OB/GYN, STD clinic, family planning); or
- A specific age group within the general population of children 0 through 18 years of age.

Specialty providers only need to supply and administer the specific vaccines recommended for the population they serve. A birthing hospital that only supplies the birth dose of hepatitis B vaccine is an example of a specialty provider.

PATIENT ELIGIBILITY

All children 0 through 18 years of age who are eligible for the federal Vaccines for Children (VFC) program, the Idaho Immunization Assessment, and federal funds for designated targeted populations may receive vaccines supplied by the IIP. **Patient eligibility must be screened and documented for every child at each immunization visit**. Patient eligibility status information must be retained and easy to retrieve in the patient's medical record for three (3) years.

VFC Eligibility

All providers must screen every child for VFC eligibility at each immunization visit. VFC eligibility does not have to be verified by the provider, but must be documented. All children 0 through 18 years of age who meet one of the following criteria are considered VFC eligible:

- Is a Native American or Alaska Native;
- Is enrolled in Medicaid;
- Has no health insurance; or
- Is underinsured. Underinsured children have private health insurance but the coverage does not include vaccines; the coverage includes only selected vaccines (the child is VFC eligible for non-covered vaccines); or, children whose insurance caps vaccine coverage at a certain amount (once the coverage amount is reached, these children are categorized as underinsured). Underinsured children are eligible to receive VFC vaccine only through a Federally Qualified Health Center (FQHC), Rural Health Clinic (RHC), or deputized Public Health District.

Private providers must inform parents of underinsured children that free vaccine may be available at a FQHC, RHC, or Public Health District. If a child qualifies for more than one category, then the provider must select the eligibility category that will require the least out-of-pocket expenses to the parent or guardian for the child to receive immunizations.

State-Eligibility

All children 0 through 18 years of age whose custodial parent or legal guardian resides in Idaho, and who are not eligible for the federal VFC program, are eligible for state-supplied vaccines provided by the IIP and funded through the Idaho Immunization Assessment.

Situations may occur where a child may have private health insurance and Medicaid as secondary insurance. These children will be VFC-eligible as long as they are enrolled in Medicaid; however, the parent or guardian is not required to participate in the VFC program.

BILLING

The main premise of the VFC Program is to supply vaccine at no cost to eligible children. There are two costs associated with vaccine— the cost of the vaccine and the administration fee. Providers must select and document the eligibility category that will require the least amount of out-of-pocket expense to the parent/guardian for the child to receive necessary immunizations.

Vaccine

- Providers may not charge patients and may not receive reimbursement for vaccine received from the IIP.

Administration Fee

- The reimbursement rate set by the Centers for Medicare & Medicaid Services (CMS) of $20.13 per dose (not per antigen) may be charged for vaccine administered to Idaho VFC-eligible, non-Medicaid children.
    - VFC-eligible, non-Medicaid = Native American, Alaska native, no insurance, or underinsured.
- The reimbursement rates set by Idaho Medicaid may be charged for vaccine administered to children enrolled in Medicaid (per dose or per antigen).
- The reimbursement rates set by contracted medical health plans may be charged for vaccine administered to children with private health insurance coverage for immunizations (per dose or per antigen).

Providers must not deny administration of vaccine supplied by the IIP to an established patient because of the child's parent or guardian's inability to pay the administration fee.

NATIONAL CHILDHOOD VACCINE INJURY ACT REQUIREMENTS

The National Childhood Vaccine Injury Act (NCVIA) of 1986 was enacted to provide a cost-effective arbitration and compensation system for vaccine injury claims and reduce the potential liability of vaccine manufacturers. It also created a system for reporting and tracking adverse events related to vaccinations. Health care professionals must adhere to the following NCVIA requirements when administering vaccinations. Please note that these requirements apply to all vaccinations administered at your facility, not just those supplied by the IIP.

Vaccine Information Statements (VIS)

VISs are published by the CDC and provide information to vaccine recipients about the risks and benefits of each vaccine. **Federal and State laws require providers to supply a current vaccine-specific VIS to each patient or each patient's legal guardian at every immunization visit, prior to the administration of the vaccine.**

VISs are updated periodically, and the CDC maintains current print, audio, and foreign language versions on their website at http://www.cdc.gov/vaccines/hcp/vis/index.html. In addition, organizations may order VISs from the IIP online resource order form at http://www.keysurvey.com/votingmodule/s180/f/548255/1140/. Whether managed as electronic or paper documents, in a paper folder or through an electronic health record (EHR), clinics must provide *current* VISs to patients. Offices using EHRs must be sure the date of the VISs being distributed is the same date documented in the patient's medical record. The IIP recommends storing all VISs in one location and designating a staff person to be responsible for keeping the VISs current.

Vaccine Adverse Events Reporting System (VAERS)

VAERS is a national vaccine safety surveillance program created through NCVIA and co-sponsored by the CDC and the Food and Drug Administration (FDA). VAERS provides a nationwide system for reporting, analyzing, and publishing information on adverse events related to vaccines. The VAERS website is https://vaers.hhs.gov/professionals/index. VAERS reporting may be conducted online at the VAERS website or VAERS reporting forms may be ordered from the IIP's online resource order form.

Reportable Events – Required

The NCVIA requires healthcare providers to report:

- Any adverse event listed by the vaccine manufacture as a contraindication to further doses of the vaccine; or
- Any adverse event listed in the VAERS Table of Reportable Events Following Vaccination (https://vaers.hhs.gov/resources/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf) that occurs within the specified time period after vaccination.

Vaccine Charting Requirements

The NCVIA requires that vaccination records be included in a patient's permanent medical record and that they include the following information:

- Type of the vaccine (DTaP, MMR, etc.);
- Vaccine lot number;
- Date of administration (month, day, year);
- Name of the vaccine manufacturer;
- Name and title of the person giving the vaccine;
- Address of the clinic where the vaccine was given;
- Specific site where the vaccine was administered (left deltoid, intranasal, etc.); and
- Publication date of the VIS and the date it was provided to the patient.

The expiration date of the vaccine is recommended by the American Academy of Pediatrics (AAP) but is not required to be documented in a patient's medical record.

SITE VISIT

The CDC requires the IIP to periodically visit providers, who receive vaccine from the IIP, to assess compliance with program requirements. The goal of the IIP is to ensure provider compliance through effective communication, and a site visit should be considered more of an educational opportunity than an audit. Most program compliance issues are addressed through education and follow-up. Only cases of repeated and intentional non-compliance progress to corrective actions.

VFC Visit

Providers can expect a visit from the IIP at least every other year. VFC visits help determine a provider's compliance with VFC program requirements. This includes identifying potential issues with VFC accountability and determining whether vaccines are being handled, stored, and administered in accordance with the laws and policies governing the VFC program.

AFIX (Assessment, Feedback, Incentives, and eXchange) Review

The IIP expects to conduct AFIX visits with at least 25% of providers each year. The AFIX visits are used for improving immunization rates and practices. The AFIX component, once understood and implemented, can assist practices in increasing immunization coverage levels and decreasing missed vaccination opportunities.

After the IIP schedules a VFC or AFIX visit with a provider's office, communication will be sent to the primary vaccine coordinator confirming the date and time. VFC and AFIX visits may take from 2 to 4 hours depending on the size of your clinic, whether both visits are conducted the same day, and any compliance issues that may arise. During the visit, the primary and back-up vaccine coordinators must be available and any key staff involved in immunizations should also be available.

Storage and Handling Visit

Providers may receive an unannounced storage and handling visit from the IIP at any time. Storage and handling visits will focus on vaccine management in a provider's office, specifically vaccine storage practices and equipment. Storage and handling visits should take no longer than 30 minutes, unless concerns are discovered.

Educational Visits

Educational visits may be conducted by the IIP or local public health district staff. The purpose of educational visits is to provide guidance and direction and not to assess compliance. Educational visits will be conducted with any organization not receiving a VFC visit during the calendar year. In addition, a need focused education visit may be conducted for non-compliance. Finally providers may request additional training online at www.immunizeidaho.com. Educational visits will vary in length depending on the topic covered, the number of attendees, and the non-compliance issues that are being addressed.

At the end of some site visits, the clinic will receive feedback and a list of any required corrective action plans with deadlines for completion. If follow-up action is required, then provider staff must carry out corrective action(s) by the deadline(s). IIP staff will follow-up by telephone, email, mail, or in-person.

FRAUD AND ABUSE

Fraud

Fraud is an intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to him or some other person. It includes any act that constitutes fraud under applicable federal or state law.

Abuse

Abuse is provider practices that are inconsistent with sound fiscal, business, or medical practices and result in an unnecessary cost to the IIP (and/or including actions that result in an unnecessary cost to Medicaid, a health insurance company, or patients); or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care.

The IIP is required to report any suspected fraud and abuse to state and federal authorities for further investigation.

Examples of Fraud and Abuse

- Providing IIP supplied vaccine to non-eligible patients.
- Selling or otherwise misdirecting vaccine supplied by the IIP.
- Billing a patient or third party for vaccine supplied by the IIP.
- Charging more than the established CMS maximum regional charge for administration of a VFC-funded vaccine to a VFC-eligible non-Medicaid child.

- Not providing eligible children vaccine supplied by the IIP because of parents' inability to pay for the administration fee.
- Not implementing provider enrollment requirements of the IIP.
- Failing to screen for and document eligibility status at every visit.
- Failing to maintain VFC records and comply with other requirements of the VFC program.
- Failing to fully account for all vaccine supplied by the IIP.
- Failing to properly store and handle vaccine supplied by the IIP.
- Ordering vaccine in quantities or patterns that do not match provider profile or otherwise involve over-ordering doses of vaccine supplied by the IIP.
- Waste of vaccine supplied by the IIP.

RESOURCES

The IIP has related forms and educational resources available at no cost to providers. Resources available from the IIP can be ordered online at www.immunizeidaho.com 24 hours a day, seven days a week. Resource orders will be shipped within 7 – 10 business days. Examples of resources available include:

- Vaccine Information Statements (VIS)
- Temperature Log Sheets
- Vaccine Bins and Labels
- Clinic Immunization Record and History/Administration Forms (includes VFC Patient Eligibility Screening Form questions)
- VAERS (Vaccine Adverse Events Reporting System) Report Forms
- Lifetime Immunization Records
- Childhood and Adolescent Brochures

TECHNICAL ASSISTANCE

IIP staff members are available to answer questions or provide additional immunization information. The IIP may be reached by phone (208) 334-5931 or by email IIP@dhw.idaho.gov Monday through Friday between 8:00 A.M. and 5:00 P.M. Mountain Time.

For questions about IRIS, please contact the IRIS help-desk by phone (208) 334-5995 or email IRIS@dhw.idaho.gov. Requests for IRIS usernames and password resets must be submitted online at http://healthandwelfare.idaho.gov/Health/IdahoImmunizationProgram/InformationforHealthcareProviders/IRIS/RequestanIRISAccount/tabid/2305/Default.aspx.

Additional information and online web education can also be found 24 hours a day, seven days a week at www.immunizeidaho.com.

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VACCINE MANAGEMENT (STORAGE & HANDLING)

PERSONNEL

Providers must designate one staff member to be the primary vaccine coordinator and at least one back-up vaccine coordinator. The back-up vaccine coordinator must be able to perform the same responsibilities as the primary vaccine coordinator in the event that the primary is unavailable. These positions will be responsible for key requirements and will provide oversight for all vaccine management within the office. The responsibilities of the designated vaccine coordinator and back-up include the following vaccine management activities:

- Documenting the temperature, twice a day during normal operating hours, on a temperature log for each vaccine storage unit, including time and name/initials of reviewer;
- Downloading temperatures each time a vaccine order is placed, and saving the temperature information in a file for review;
- Adjusting the temperature of a vaccine storage unit, if needed;
- Reviewing the temperature logs weekly when daily monitoring is being conducted by a back-up person to ensure proper temperature recording. The back-up vaccine coordinator will monitor the temperature logs if the primary coordinator is unavailable;
- Training all staff involved with vaccines at least annually;
- Documenting all staff training, including the date(s) of training, topics covered, and staff attending;
- Following the office's vaccine management storage and handling plans, including reviewing the plan annually and making changes as needed throughout the year;
- Documenting all updates and reviews of the vaccine management storage and handling plans; and
- Notifying the IIP, by email at IIP@dhw.idaho.gov, as soon as any changes have been made to the primary or back-up vaccine coordinators.

REQUIRED PROVIDER EDUCATION

All primary and back-up vaccine coordinators must complete VFC compliance and storage and handling training annually. All trainings must be documented.

How to Meet the Annual Training Requirement

Vaccine coordinators can meet the annual training requirements by completing one or more items below:

- ☐ Participate in an Enrollment Visit.
- ☐ Participate in a VFC Visit.
- ☐ Participate in an Educational Visit conducted by local public health district staff.
- ☐ Complete two web-based training modules. *CDC's You Call the Shots*: Vaccine Storage and Handling, and Vaccines for Children (VFC) located at http://www.cdc.gov/vaccines/ed/youcalltheshots.htm.
    - After the training is complete, print the certificate of completion. Document your name and the date of the training and keep a copy on file for review by the IIP.

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REQUIRED WRITTEN PLANS

Providers must have written routine vaccine management and emergency storage and handling plans. Providers may develop their own written routine and emergency storage and handling plans or use the IIP supplied Vaccine Management Storage and Handling template. Both the routine and the emergency plans should be presented in a clear and concise manner and must be reviewed at least annually.

Vaccine Management Plan

A routine vaccine management plan should include guidance on the following:

- ☐ Names of the current primary and back-up vaccine coordinators for the office
- ☐ Ordering vaccines
- ☐ Maintaining inventory
- ☐ Storing and handling vaccines and monitoring storage conditions
- ☐ Vaccine expiration, spoilage, and wastage prevention
- ☐ Vaccine shipping, including receiving, packing, and transporting
- ☐ Staff training, with documentation of training, on IIP requirements including proper vaccine storage and handling
- ☐ Name, title, and signature of document preparer
- ☐ Name of document reviewer and date of annual review and/or plan updates

Emergency Vaccine Plan

An emergency storage and handling plan should include guidance on what to do in the event of refrigerator or freezer malfunctions, power failures, natural disasters, or other emergencies that might compromise appropriate vaccine storage conditions. The emergency plan should include the following:

- ☐ Person(s) responsible for preparing and transporting vaccine, including contact information
- ☐ How this person will be notified that vaccine needs to be moved
- ☐ Alternative storage unit or facility
  - Must be a storage unit where temperatures have been and will continue to be monitored.
  - May not be a personal refrigerator or freezer at home.
- ☐ How receiving location will be notified of transport
- ☐ How to pack vaccine for transport
- ☐ Up-to-date list of vaccine manufacturer phone numbers

VACCINE STORAGE UNITS

Providers must have appropriate equipment that can store vaccine and maintain proper conditions. All VFC providers must have acceptable storage units (listed below) prior to the enrollment visit and receiving vaccine. Any time a provider's office does not have acceptable storage units, vaccine will not be shipped.

Current acceptable storage units are:

- A stand-alone refrigerator and stand-alone freezer; or
- A combination unit with separate doors, dual controls, and with a separate freezer condenser and a separate refrigerator condenser with no air vents connecting the two.

  Note: Providers enrolled in the program before October 1, 2012 may continue to use the refrigerated portion only of a single –condenser combination unit (must have separate doors and temperature controls).

The use of dormitory style or bar-style refrigerators is not allowed at any time for storage of vaccine. A dormitory style refrigerator is defined as a small combination refrigerator/freezer unit that is outfitted with one exterior door and an evaporator plate (cooling coil), which is usually located inside an icemaker compartment (freezer) within the refrigerator.

Cooling or evaporator plates, located inside the unit, are not allowed for the storage of vaccine received by the IIP.

Note: Providers enrolled in the program before October 1, 2012 and who purchased a storage unit prior to March 14, 2014, may continue to use a storage unit with a cooling/evaporator plate until further notice; however, any storage units purchased after March 15, 2014 with cooling/evaporator plates will not be approved by the IIP for vaccine storage.

Refrigerators or freezers used for vaccine storage must comply with the following requirements:

- Be able to maintain required vaccine storage temperatures year-round.

Refrigerator	35° to 46° F	2° to 8° C
Freezer	-58° to +5° F°	-50° to -15° C

- Be large enough to hold the year's largest inventory without crowding.
- Be large enough to store water bottles in the refrigerator and frozen coolant packs in the freezer to stabilize the temperature.
- Be frost-free or automatic defrost cycle units (recommended).
- Be dedicated to vaccine storage.
    - Food and beverages are not to be stored in a vaccine storage unit.
    - If biologicals must be stored in the same unit, then they must be stored below the vaccine. In addition, the vaccine is the priority in the storage unit. If the biologicals inhibit vaccines from being stored appropriately, then the biologicals must be removed from the vaccine storage unit.

TEMPERATURE RECORDING DEVICES

All vaccine storage units must be equipped with calibrated, continuous recording temperature monitoring devices that can measure both the minimum and maximum temperatures. Temperature monitoring devices must be covered by a Certificate of Traceability and Calibration. The traceability declaration is to confirm that the measurement standards and instructions used during calibration of the product are traceable to an ISO/IEC 17025 accreditation testing laboratory or to the National Institute of Standards and Technology. The current certification and calibration information must be on file with the IIP in order to receive vaccines supplied by the IIP.

The IIP supplies a temperature recorder for use in the refrigerator and freezer. The IIP will supply one recorder for each 24-hour storage unit that holds vaccine supplied by the IIP. The IIP will maintain the temperature recorders supplied, including calibration. If a temperature recording unit is disposed of or damaged, then the provider will be responsible for replacement of the recorder. In addition, one communicator will be supplied to each provider office. Providers will also be responsible for the replacement of a damaged or disposed of communicator. The probe with nylon buffer must be placed in the center of the refrigerator and inside the freezer next to the frozen vaccine.

Providers are not required to utilize the temperature recorder supplied by the IIP. If a provider's office uses a different temperature monitoring device, then the following requirements must be met and the device approved for use by the IIP:

- Use of a calibrated and certified unit to an accuracy of +/- 1° F (0.5°C)
    - Current calibration information must be on file with the IIP. Vaccine cannot be shipped to an office if a current calibration certificate has not been submitted.
- Use of a continuously recording unit
    - Current temperature displayed outside of unit
    - Memory storage of at least 4,000 readings
    - Temperatures are recorded at a minimum interval of every 15 minutes
    - Hi/Lo alarm for out-of-range temperatures
- Use of a biosafe glycol-encased probe or similar temperature buffered probe

ROUTINE VACCINE STORAGE AND HANDLING REQUIREMENTS

The vaccine storage practices listed below are the responsibility of the primary vaccine coordinator and can be delegated to the back-up vaccine coordinator. If the practices are delegated, then the primary vaccine coordinator must monitor the activity.

- Store refrigerated vaccine at 35° to 46° F (2° to 8° C)
- Store frozen vaccine at -58° to +5° F (-50° to -15° C)
- Store vaccines requiring refrigeration in the middle of the refrigerator compartment away from the coils, walls, floor, and cold air vent
- Store vaccines that require freezer storage in the middle of the freezer compartment, away from the walls, coils, and peripheral areas
- Space stored vaccine to allow for cold air circulation around the vaccine
- Only store vaccines in the refrigerator and freezer
- Do not store vaccines in the door or in the drawers of the storage unit
- Remove vegetable bins from the refrigerator and replace with cold water bottles
- Stabilize refrigerator and freezer temperatures with proper placement and use of water bottles in the refrigerator and frozen packs in the freezer
- Store vaccine in their original packaging with the lids closed and in place until ready to administer to protect them from sunlight and fluorescent light
- Store vaccine products that have similar packaging in different locations to avoid confusion and medication errors
- Rotate vaccine stock by placing vaccines with shorter expiration dates in front of those with longer expiration dates; check for short-dated vaccine weekly
    - Notify the IIP, in writing, within 3 months (90 days) of any vaccine doses that will expire before they can be administered. Only with the approval and direct guidance of the IIP and only if the cold chain can be ensured, redistribute short-dated vaccines to providers who are able to administer them before the vaccines expire.
- Immediately remove expired vaccine from the storage unit
- Prepare vaccines immediately prior to administration. Pre-drawing vaccine into syringes is <u>not</u> an acceptable practice
- "Do not unplug" stickers must clearly mark all electrical outlets and circuit breakers of every vaccine storage unit

- Vaccine storage units are not plugged into GFI outlets (with a red reset button), outlets that can be activated by a wall switch, or multi-outlet power strips.

If a provider has privately purchased vaccine, then the vaccine must be marked and/or separated from the vaccine supplied by the IIP. Suggestions to differentiate between vaccines:

- Utilize State-Supplied stickers (blue) provided by the IIP
- Place vaccine on separate, marked shelves
- Place vaccine in separate storage units

VACCINE ORDERING

Vaccines can be ordered 24 hours a day, seven days a week through IRIS. Providers must order vaccines in accordance with actual vaccine need within their ordering cycle (see Economic Ordering Quantity section below). Current storage temperatures and physical on-hand vaccine counts must be submitted before a vaccine order can be created in IRIS. Emergency orders will only be placed in response to a disease outbreak or natural disaster.

ECONOMIC ORDERING QUANTITY (EOQ)

EOQ balances provider order size, order frequency, the timing of orders, and storage and handling to minimize costs and improve efficiencies as orders flow through the system. The IIP will notify providers of their designated ordering frequency. Providers are asked to place orders and plan inventory supply based on the assigned EOQ; however, EOQ is not intended to keep providers from ordering vaccine anytime there is a need. In addition, providers may contact the IIP to request a change to the assigned EOQ.

Providers will place orders based on an ordering frequency determined by the number of vaccines ordered, the number of vaccines administered, and the size of the storage unit(s). Depending on the volume, the ordering frequency may be monthly (once a month), bi-monthly (every other month), quarterly (every third month), or semi-annually (twice a year).

VACCINE BRAND CHOICE

Providers may choose which vaccine brands to supply when competing vaccines are available. For example, there are two manufactured for hepatitis A vaccine. Each clinic will determine which hepatitis A vaccine to supply. Brand choice must be submitted in writing, by completing the IIP Vaccine Brand Choice Form (which can be found online at www.immunizeidaho.com).

Vaccine brand choices may be changed twice a year with changes taking place in January and July. Providers who decide to change vaccine brands are still responsible to use the vaccine stock currently on-hand.

RECEIVING VACCINE SHIPMENTS

Refrigerated vaccines are shipped from McKesson Specialty Distribution, LLC. Varicella containing vaccines are shipped directly from the manufacturer (Merck). After vaccine orders are processed, they may take up to 14 days to ship.

Vaccines must be shipped directly to the offices where the vaccine will be administered. The IIP may grant exceptions for providers with multiple sites; however, a memorandum of understanding must be issued by the IIP if vaccines will not be directly shipped to an office. Frozen vaccines must be directly shipped to the

office where they will be administered.

Upon receipt of a vaccine shipment, providers must:

- Open the vaccine shipment immediately;
  - Check the temperature monitor reading;
  - Inspect the vaccine and packaging for damage;
  - Determine the length of time the vaccine was in transit by looking at the packing list;
  - Compare the vaccine received with the vaccine products that appear on the packing list;
    - Contact McKesson Specialty at 1-877-822-7746 with any discrepancy/damage within 2 hours of receiving the vaccine shipment.
- Immediately store the vaccine at the appropriate temperatures (place in the vaccine storage units); and
- If no discrepancies/damage, then accept the vaccine into the provider's inventory in IRIS.

VACCINE INVENTORY

The IIP purchases an average of $35 million dollars of vaccine annually and distributes an average of 750,000 doses of vaccine each year.

Providers are responsible to account for all doses of vaccine supplied by the IIP. Accountability is completed in IRIS. A physical on-hand count of the vaccine is required each time vaccine is ordered. The count must be submitted through IRIS. Monthly inventory counts are considered "best practice" and the IIP encourages providers to count inventory on a monthly basis.

Providers who fail to report accurate on-hand counts may not be shipped vaccine. All vaccine shipments must be accepted into the organization's IRIS inventory and all doses of wasted vaccine must be accounted for in IRIS. In addition, all doses of vaccine supplied by the IIP must be entered into IRIS within 45 days of administration. If the inventory counts become too far off (difference between IRIS inventory and provider's physical inventory), then provider orders may not be approved until counts can be reconciled. Unaccounted for or lost vaccine may be subject to replacement by the provider office (see Vaccine Loss and Replacement section below).

Vaccine Borrowing

Borrowing a vaccine supplied by the IIP to administer to a patient who is not eligible for the vaccine is not allowed. If providers plan to vaccinate patients who are not eligible for the vaccines supplied by the IIP, then they are expected to maintain adequate stock of privately purchased vaccines for those patients.

On rare occasions, a provider's private vaccine stock may be used for a child eligible for the vaccine supplied by the IIP or a provider may inadvertently administer a vaccine supplied by the IIP to an ineligible patient. A dose-for-dose replacement of vaccine stock must be made. The provider must document the instance, complete the IIP Vaccine Replenishment Report, submit the report to the IIP, and make appropriate adjustments to IRIS inventory.

Expired, Spoiled, Wasted Vaccine

The IIP must be notified of expiring vaccine at least 3 months (90 days) prior to the vaccine's expiration date if the vaccine will not be used. To report expiring vaccine, email IIP@dhw.idaho.gov or fax (208) 334-4914 with the vaccine type, brand, lot number, expiration date, and the number of doses. A provider may be required

to replace expired vaccine supplied by the IIP, if the IIP was not notified 3 months (90 days) prior to the expiration date (see Vaccine Loss and Replacement section below).

Expired or Spoiled Vaccine is nonviable vaccine in its original container (vial or syringe) that is returned to McKesson Specialty Distribution, LLC for federal excise tax credit. The expired or spoiled vaccine must be reported to the IIP within four weeks of loss and the vaccine must be returned to McKesson within six months of loss. Returnable vaccine includes expired vaccine or vaccine that has been spoiled as a result of the following:

- Natural disaster / power outage
- Refrigerator too warm or too cold
- Failure to store properly upon receipt
- Vaccine spoiled in transit
- Mechanical failure (of vaccine storage unit)
- Spoiled (vaccine in its original packaging that has been destroyed by another means, not listed here)
- Recall (vaccine that has been recalled)

Wasted Vaccine is nonviable vaccine that cannot be returned for federal excise tax credit. Wasted vaccine needs to be reported to the IIP at least with each vaccine order. Wasted vaccine includes the following:

- Broken vial/syringe
- Vaccine drawn up into syringe but not administered
- Lost or unaccounted for vaccine
- Non-vaccine products (e.g. IG, HBIG, diluent)
- Open vial that all the doses have not been administered

For instructions on vaccine returns and the reporting forms to use, please see the IIP Vaccine Incident Report and Vaccine Return Form Instructions and Guidelines located on the Forms tab in IRIS and at www.immunizeidaho.com.

TEMPERATURE MONITORING

Providers must store vaccines at the appropriate temperatures. The temperature range for refrigerated vaccines is **35°–46°F** (2°C–8°C). Frozen vaccine must be kept between **-58°F–(+5°F)** [-50°C– (-15°C)]. ***Failure to store vaccine at the proper temperature can seriously compromise or destroy vaccine efficacy***.

Record refrigerator and freezer temperatures twice each day during normal operating hours (at the beginning and end of each day), ensuring that refrigerator and freezer temperatures are within range. Twice-daily temperature monitoring and recording is required even if a continuous graphing/recording thermometer or a digital data logger is used. The actual temperature is required for documentation. An "x" or "✓" is not acceptable. In addition, the time of the temperature and the reviewer's name/initials are also required. The IIP supplies a temperature log for providers to use; however, providers may use a different method to document the required information twice a day. Temperature logs must be complete and stored for three years.

Temperature Incidents (Out of range temperatures)

Immediate corrective action must be taken when vaccine storage temperatures are found to be outside of the acceptable temperature ranges. Providers **must notify the IIP** by calling 208-334-5931 any time temperatures are outside of the appropriate range. After determining the scope of the temperature incident, the program will work with the provider and vaccine manufacturers to assist in determining if the vaccines are still viable.

450 W State Street 4th FL
Boise, Idaho 83702
(208) 334-5931

Unreported Temperature Incidents

Providers who fail to report a temperature incident when vaccines are stored outside the normal temperature range for more than 2 hours will be placed on probation for 1 year. As a condition of the probation:

- The provider must correct the problem and submit monthly temperature logs along with monthly inventory counts for 1 year;
- In-office training provided by IIP staff on vaccine storage and handling will be offered to the provider's immunization staff;
- The IIP will make recommendations for follow-up action based upon ACIP recommendations; and
- Depending on the duration and individual circumstances of the incident, the Department of Health and Welfare may take additional measures as deemed necessary.

In the event that a provider has a second unreported temperature incident either during the probation period or within the two years following the probationary period:

- The provider, along with their entire immunization and office staff, will be required to attend an in-office training provided by the IIP on vaccine storage and handling;
- The IIP will make recommendations for follow-up action based upon ACIP recommendations; and
- The Department of Health and Welfare may take additional measures as deemed necessary.

In the event of a third unreported temperature incident either during the probation period or within the two years following the probationary period:

- The IIP may terminate the Provider Agreement with the provider for failure to comply with the program requirements.

VACCINE LOSS AND REPLACEMENT

As a provider enrolled in the IIP, you are entrusted with federal and state purchased vaccine to immunize children at *no cost;* however, **providers will be required to replace vaccines lost due to provider negligence.**

Situations That Require Vaccine Replacement

Below is a list of situations that are considered provider negligence and may require a provider to replace lost or wasted vaccines dose-for-dose. This list is not exhaustive. Failure of a provider or staff to adhere to the current *IIP Provider Agreement* and *Policies and Guidelines* will result in a restitution situation. Restitution will be in the form of a dose-for-dose replacement. Situations that occur which are not listed here will be considered on an individual basis by the IIP.

- A vaccine inventory wastage (loss) of 5% or greater (including unaccounted for vaccine).
- Provider fails to log temperatures twice daily during normal operating hours and temperatures are found to be out-of-range resulting in vaccine loss.
- Provider fails to rotate or request to transfer vaccine that results in expired vaccine (the IIP was not notified 90 days before the vaccine was to expire).
- Vaccines are drawn up prior to patient screening (pre-drawing vaccine).
- Provider storage and handling mistakes.
- Vaccine that is left out of the refrigeration unit and becomes non-viable.
- Freezing vaccine meant to be refrigerated.
- Refrigerating vaccine meant to be frozen.
- A refrigerator left unplugged or electrical breaker switched off.

- A refrigerator door left open or ajar.

- Refrigerator/freezer equipment problems where proof of repair or equipment replacement is not provided to the IIP within 30 days from the date of discovery.
- Any power outages in which the provider fails to act according to the posted plan.
- IIP-supplied vaccine is administered to a non-eligible patient (see Vaccine Borrowing)

Providers are responsible for the cost of re-vaccination due to negligence.

Procedures for Vaccine Replacement

- After the provider supplies the IIP with a copy of the *McKesson Vaccine Return Form*, *Temperature Incident Report*, and *Wasted Vaccine Form*, the provider must replace each dose of vaccine wasted/lost.
- The provider will submit a list of replacement vaccine doses with lot numbers to the IIP to be entered into the provider's inventory in IRIS.

Situations That Do NOT Require Vaccine Replacement

Below is a list of situations that are not considered provider negligence. This list is not exhaustive. In these situations, the provider is deemed not to be at fault. Providers may be required to produce a letter from the alarm/alert company or the power company.

- Vaccine shipment is not delivered to the provider in a timely manner or is otherwise damaged or stored improperly during transit. Before making the determination that the vaccine is non-viable, store the vaccine appropriately and then call the IIP.
- A provider who has a current contract with an alert/alarm company and has a refrigerator that malfunctions and the alarm/alert company does not notify the provider.
- A provider moves vaccine to a location with a secure power source due to anticipated inclement weather, the location experiences a power failure, and the vaccine is later deemed not viable.
- Power was interrupted or discontinued due to acts of nature, and after consultation with the IIP, it is determined that vaccine is not viable.
- A vial that is accidentally dropped or broken by a provider.
- Vaccine that is drawn up after screening for contraindications and parental education, but not administered due to parental refusal or a change in physician orders.
- Expired vaccine that is not due to provider negligence (including seasonal influenza vaccine).
- Refrigerator/freezer equipment problems where proof of repair or equipment replacement is provided to the IIP within 30 days from the date of discovery.
- Extraordinary situations not listed above which are deemed by the IIP to be beyond the provider's control.